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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/574,781	04/06/2006	Rolf Gericke	MERCK-3158	2544
23599 7590 09/19/2007 MILLEN, WHITE, ZELANO & BRANIGAN, P.C. 2200 CLARENDON BLVD. SUITE 1400 ARLINGTON, VA 22201			EXAMINER POWERS, FIONA	
			ART UNIT 1626	PAPER NUMBER
			MAIL DATE 09/19/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	10/574,781	GERICKE ET AL.	
	Examiner	Art Unit	
	Fiona T. Powers	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 03 August 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) 7-14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6, 15 and 16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4/6/06</u>  | 6) <input type="checkbox"/> Other: _____                          |

Receipt is acknowledged of the information disclosure statement filed April 6, 2006, which has been entered in the file. The non-US Patent documents cited by applicants have been crossed out since copies of these references are not of record in the file.

Applicant's election with traverse of Group I (claims 1-6, 15 and 16) and the species of Example 1 on page 26 in the reply filed on August 3, 2007 is acknowledged. The traversal is on the ground(s) that all of the claims in the application involve related subject matter and the Office Action has not demonstrated that an undue searching burden would be required to examine all groups. This is not found persuasive because the claims lack unity of invention because the compounds of formula I are known in the art. See the rejections which follow. In addition, it would be an undue burden on the examiner and the patent office resources to examine all of the claims since separate search considerations are required to examine groups I and II. For example, the compounds of Group I are classified in various subclasses of classes 558, 564 and 562, whereas the method claims of Group II are classified in various subclasses of class 514.

The requirement is still deemed proper and is therefore made FINAL.

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Claims 7 to 14 stand withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on August 3, 2007.

Claims 2 and 5 are objected to because of the following informalities: in claim 2, in the definition of  $R^2$  a comma should be added between "Hal" and "OA". Also in claim 2, in the definition of  $R^4$ , a comma should be added after "OA". In claim 5, on page 6, line 17, for "dimethoxyphenyl[" the bracket should be deleted. Appropriate correction is required.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 to 6, 15 and 16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification does not describe all possible "pharmaceutically usable derivatives". The only derivatives described are salts and prodrugs. To overcome this rejection the term "derivative" should be replaced by -prodrug-.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2 and 6 are rejected under 35 U.S.C. 102(a) as being anticipated by Pandeya et al. (Acta Pharmaceutica (Zagreb, Croatia), 53(1), 15-24, 2003), cited.

The reference discloses the claimed compounds of the formula I wherein  $R^1$  to  $R^5$  are selected from H, OH, Cl,  $NH_2$  and  $NO_2$ ;  $R^6$  to  $R^{10}$  are selected from H and Br;  $R^{11}$  is H or  $CH_3$ ; and X is  $OCH_2$ . Note Compound Nos. 8a to 8l, 8n and 8q of Table II on page 19. The compounds are medicaments with anticonvulsant properties.

Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has

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not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

Claims 1 and 6 are rejected under 35 U.S.C. 102(a) as being anticipated by Muanprasat et al. (Journal of General Physiology, 124(2), 125-137, August 2004), cited.

The reference discloses the claimed compound wherein R<sup>1</sup> and R<sup>3</sup> are OH; R<sup>2</sup> and R<sup>4</sup> are Br; R<sup>5</sup> to R<sup>7</sup>, R<sup>9</sup> and R<sup>10</sup> are H; R<sup>8</sup> is CH<sub>3</sub>; R<sup>11</sup> is H; and X is CH<sub>2</sub>. Note the compound AceH-403 of Table 1 on page 131. The compound is a medicament that is a CFTR inhibitor.

Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

Claims 1, 2 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Pandeya et al. (Pharmazie, 56(2), 121-124, 2001), cited.

The reference discloses the claimed compounds of the formula I which are medicaments wherein R<sup>1</sup> to R<sup>5</sup> are selected from H, OH, Cl and OCH<sub>3</sub>; R<sup>6</sup> to R<sup>10</sup> are H; R<sup>11</sup> is H or CH<sub>3</sub>; and X is CH<sub>2</sub>. Note Compounds 1a to 1c and 1f to 1h of Table 1.

Claims 1 to 3 are rejected under 35 U.S.C. 102(b) as being anticipated by Issa et al. (Synthesis and Reactivity in

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Inorganic and Metal-Organic Chemistry, 31(1), 95-105, 2001), cited.

The reference discloses the claimed compounds of the formula I wherein  $R^1$  is OH;  $R^2$  is H;  $R^3$  is H or OH;  $R^4$  to  $R^{11}$  are H and X is  $-\text{CH}(\text{OH})-$ . Note the mandelic hydrazones where Y is H or 4-OH in Figure 2.

Claims 1, 2 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Markham et al. (WO 01/70213), of record.

The reference discloses the claimed compounds of the formula I which are medicaments wherein  $R^1$  is OH;  $R^2$  is  $\text{OCH}_3$ ;  $R^3$  to  $R^7$  and  $R^9$  to  $R^{11}$  are H;  $R^8$  is  $\text{CH}_3$ ; and X is  $\text{CH}_2$ . Note Compound No. 1044 of the table on page 54.

Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Kotali et al. (Chemical Abstracts, 125:561410, 1996), of record.

The reference discloses the claimed compounds of the formula I wherein  $R^1$  is OH;  $R^2$  to  $R^{10}$  are H;  $R^{11}$  is  $\text{CH}_3$ ; and X is  $\text{OCH}_3$ . Note Registry No. 182567-86-8.

Claims 1, 2 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Dilanyan et al. (Chemical Abstracts, 125:212091, 1996), of record.

The reference discloses the claimed compounds of the formula I that are medicaments wherein  $R^1$  is OH;  $R^2$  to  $R^6$  are H;

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$R^7$  is H or Br;  $R^8$  is OA where A is  $C_1$ - $C_3$ alkyl;  $R^9$  to  $R^{11}$  are H; and X is  $CH_2$ . Note Registry Nos. 181428-40-0, 181428-47-7, 181428-53-5, 181428-59-1, 181428-64-8 and 181428-70-6.

The references made of record and not relied upon show the state of the art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fiona T. Powers whose telephone number is 571-272-0702. The examiner can normally be reached on Monday - Friday 8:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

*Fiona T. Powers*  
Fiona T. Powers  
Primary Examiner  
Art Unit 1626

ftp  
September 14, 2007